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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,100	04/17/2002	Bernhard Siebold	G-32210A/GBG	6036
1095	7590	06/04/2004	EXAMINER	
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 430/2 EAST HANOVER, NJ 07936-1080			GHALI, ISIS A D	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/031,100	Applicant(s) SIEBOLD ET AL.	
	Examiner Isis Ghali	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/26/2002</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The receipt is acknowledged of applicants' IDS, filed 03/26/2002.

Claims 1-34 are included in the prosecution.

Specification

1. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.

- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

4. The use of the trademark "Pluronic F-68" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

5. Claims 6-10, 19-21, 23-34 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend on another multiple dependent claim. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the compound" in the second line of the claim.

There is insufficient antecedent basis for this limitation in the claim.

Claims 3-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that they fail to point out what is included or excluded by the claim language and introduced by frequent use of the relative terms "optionally", "preferably", "more preferably" and "even more preferably". These claims are omnibus type claims.

Regarding claims 6, 10, 16, 21, 24, 25 and 27, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The claims are rendered indefinite by raising a question or doubt introduced by the limitations following the expression "preferably" because it is subject of more than one interpretation, and one interpretation would render the claim unpatentable over the prior art. In the present claim 6, the broad range is "pH 6.15-7.4" and the narrower range is "pH 6.2-6.5". In the present claim 10, the broad range is the concentration of non-ionic surfactant in the

range of "0.05%-5%" and the narrower range is "0.1%-1.0%". In claim 16, the broad range is the concentration of non-ionic surfactant in the range of "less than 0.05%" and the narrower range is "less than 0.04%", and the more narrow range is "less than 0.001%". In claim 21, the broad range is the percentage of aggregation of growth hormone "less than 10%" and the narrower range is "less than 1%", and the more narrow range "less than 0.1%". In the present claim 25, the broad range is the storage period "six weeks" and the narrower range is "1-4 months", and the more narrow range "3 month". In the present claim 25, the broad range is the storage temperature "2⁰C or greater", the narrower range is "4⁰C or greater", more narrow range is "2⁰C to less than 40⁰C", even narrower range is "2⁰C to 25⁰C", and most narrow range is "15⁰C". Regarding claim 27, the broad range is the detection of crystallization by "eye", the narrower range is "5X magnification" and the more narrow range is "10X".

Regarding claim 19, the term "e.g." renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 22 contains the trademark/trade name "Pluronic F-68". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or

trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe non-ionic surfactant and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-15, 17-30 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 94/03198 ('198).

WO '198 disclosed a stable pharmaceutically acceptable aqueous isotonic formulation containing human growth hormone, buffer solution, non-ionic surfactant, mannitol, preservative and water (abstract; page 3, lines 21-25; page 7, lines 1-8; page 17, claim 12). The amount of human growth hormone is 0.1 to 10 mg/ml (page 5, lines 1-16). The buffered solution included phosphate and present in range of 2 mM to 50 mM (page 6, lines 1-5). The suitable pH ranges from 4-8 (page 6, lines 15-20). The preservatives present in amount of 0.2%-1% and include phenol, benzyl alcohol, meta-cresol, methyl paraben, propyl paraben, benzalconium chloride and benzathonium chloride (page 6, lines 7-13). The non-ionic surfactant includes Pluronic in an amount of 0.1%-1% (w/v) (page 5, lines 27-34; page 16, claim 2). The formulation showed aggregation less than 1% after 18 month when stored at temperature between 2°C to

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25⁰C, and the solution was clear to the eye i.e. no crystallization (page 9, lines 8-34; page 10, lines 7-10). The formulation is administered by needleless jet injector gun (page 5, lines 38-39).

10. Claims 1-4, 7, 8, 11-15, 17, 18-20, 21, 23-27 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/07816 ('816).

US '816 disclosed stable injectable isotonic solution containing growth hormone , mannitol, pH adjusting phosphate buffer solution, benzyl alcohol as a preservative and water (abstract; page 8, Example I). The pH of the solution is 5.9 (Example I). The solution is stable for 2-6 months at temperature of about 7-25⁰C (page 6, lines 16-19; page 10, lines 7-12). The degree of aggregation of a specific compound in a formulation is inherent for the formulation having the same composition. Specific formulation will have the same degree of crystallization under the same conditions.

11. Claims 1-7, 9-15, 17, 19, 20, 23-30 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,096,885 ('885).

US '885 disclosed a stable solution comprising human growth hormone, mannitol, buffer, preservative, and nonionic surfactant (abstract; col.2, lines 65-68; col.6, line 25; col.7, lines 1-10, 54-60). The buffer is phosphate buffer (col.5, lines 1-10, 46-47). The pH of the formulation is between 4-8 (col.3, lines 1-3). The amount of surfactant is between 0.1-5% (col.6, lines 40-41). The formulation is administered by jet injector gun (col.6, lines 35-36). The degree of aggregation of a specific compound in a

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formulation is inherent for the formulation having the same composition. Specific formulation will have the same degree of crystallization under the conditions.

12. Claims 1-6, 9-11, 14, 15, 17, 19-21, 23-30 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,126,324 ('324).

US '324 discloses a liquid isotonic solution comprising human growth hormone, water, phosphate buffer, mannitol, non-ionic surfactant (col.9, lines 38-45, 50-54, 60-65; col.18, claim 4). The pH of the solution is 4.5-8 (col.10, lines 1-2). The amount of surfactant is 0.1% (col.10, lines 20-21). The formulation is injectable (col.10, lines 39-40). The degree of aggregation of a specific compound in a formulation is inherent for the formulation having the same composition. Specific formulation will have the same degree of crystallization under the same conditions.

13. Claims 1-4, 7, 8, 11-15, 17, 18-20, 21, 23-30 rejected under 35 U.S.C. 102(b) as being anticipated by US 5,567,677 ('677).

US '677 disclosed an injectable aqueous solution comprising growth hormone, buffer, mannitol, and benzyl alcohol (abstract). the buffer includes phosphate and having pH of 5.0-7.0 (col.3, lines 23-27, table I; col.8, claim 1). The formulation is stable for 12 months (col.3, lines 29-32). The degree of aggregation of a specific compound in a formulation is inherent for the formulation having the same composition. Specific formulation will have the same degree of crystallization under the same conditions.

14. Claims 1-6, 9, 11, 14, 15, 17, 19-21, 23-27 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,610,134 ('134).

US '134 disclosed a liquid formulation comprising growth hormone, water, phosphate buffer, mannitol, and non-ionic surfactant (col.12, lines 32-34, 42-46, 51-58). The pH of the formulation is from 4.5-8.0 (col.12, lines 61-62). The degree of aggregation of a specific compound in a formulation is inherent for the formulation having the same composition. Specific formulation will have the same degree of crystallization under the same conditions.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO '198.

The teachings of WO '198 are discussed under 102 rejection above.

However, WO '198 does not teach the amount of the non-ionic surfactant as claimed in claim 16.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a formulation comprising growth hormone and non-ionic surfactant as disclosed by WO '198 with the amount of the surfactant less than 0.05%, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

18. Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '198 in view of US 5,334,162 ('162).

The teachings of WO '198 are discussed under 102 rejection above.

However, WO '198 does not teach the kit having the pen injector device and a separate container of the growth hormone as claimed in claims 31-34.

US '162 teaches a cartridge assembly for administration of compounds, wherein the cartridge holds the compound and forms a portion of a pen injector device

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(abstract). The device is suitable for lyophilized compounds that are moisture and oxygen sensitive such as growth hormone (col.1, lines 42-51).

Thus, it would have been obvious to one having ordinary skill in the art the time of the invention to provide the formulation comprising growth hormone disclosed by WO '198, and administer the formulation by pen injector device comprising the growth hormone in a cartridge as disclosed by US '162, motivated by the teaching of US '162 that the device is suitable for lyophilized compounds that are moisture and oxygen sensitive such as growth hormone, with reasonable expectation of the having the formulation of WO '198 comprising growth hormone delivered by pen injector device comprising cartridge containing the hormone and deliver it to the needy patient with great success.

19. Claims 28-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '816 in view of US '162.

The teachings of both references are discussed above.

WO '816 does not teach the kit and the pen injector device as claimed in claims 28-34

Thus, it would have been obvious to one having ordinary skill in the art the time of the invention to provide the formulation comprising growth hormone disclosed by WO '816, and administer the formulation by pen injector device comprising the growth hormone in a cartridge as disclosed by US '162, motivated by the teaching of US '162 that the device is suitable for lyophilized compounds that are moisture and oxygen

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sensitive such as growth hormone, with reasonable expectation of the having the formulation of WO '816 comprising growth hormone delivered by pen injector device comprising cartridge containing the hormone and delivers it to the needy patient with great success.

20. Claims 16, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '885.

The teachings of US '885 are discussed above, however, the reference does not teach the amount of the non-ionic surfactant as claimed in claim 16, or the specific surfactant as claimed in claim 22.

The specific non-ionic surfactant claimed in claim 22 does not impart patentability to the claim because the prior art recognized the addition of non-ionic surfactant to reduce growth hormone aggregation, absent evidence to the contrary.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a formulation comprising growth hormone and non-ionic surfactant as disclosed by US '885 with the amount of the surfactant less than 0.05%, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

21. Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '885 in view of US '162.

The teachings of both references are discussed above.

US '885 does not teach the kit and the pen injector device as claimed in claims 31-34.

Thus, it would have been obvious to one having ordinary skill in the art the time of the invention to provide the formulation comprising growth hormone disclosed by US '885, and administer the formulation by pen injector device comprising the growth hormone in a cartridge as disclosed by US '162, motivated by the teaching of US '162 that the device is suitable for lyophilized compounds that are moisture and oxygen sensitive such as growth hormone, with reasonable expectation of the having the formulation of US '885 comprising growth hormone delivered by pen injector device comprising cartridge containing the hormone and delivers it to the needy patient with great success.

22. Claims 16, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '324.

The teachings of US '324 are discussed above, however, the reference does not teach the amount of the non-ionic surfactant as claimed in claim 16, or the specific surfactant as claimed in claim 22.

The specific non-ionic surfactant claimed in claim 22 does not impart patentability to the claim because the prior art recognized the addition of non-ionic surfactant to reduce growth hormone aggregation, absent evidence to the contrary.

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a formulation comprising growth hormone and non-ionic surfactant as disclosed by US '324 with the amount of the surfactant less than 0.05%, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

23. Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '324 in view of US '162.

The teachings of both references are discussed above.

US '324 does not teach the kit and the pen injector device as claimed in claims 31-34.

Thus, it would have been obvious to one having ordinary skill in the art the time of the invention to provide the formulation comprising growth hormone disclosed by US '324, and administer the formulation by pen injector device comprising the growth hormone in a cartridge as disclosed by US '162, motivated by the teaching of US '162 that the device is suitable for lyophilized compounds that are moisture and oxygen sensitive such as growth hormone, with reasonable expectation of the having the formulation of US '324 comprising growth hormone delivered by pen injector device comprising cartridge containing the hormone and delivers it to the needy patient with great success.

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24. Claims 16, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '677.

The teachings of US '677 are discussed above, however, the reference does not teach the amount of the non-ionic surfactant as claimed in claim 16, or the specific surfactant as claimed in claim 22.

The specific non-ionic surfactant claimed in claim 22 does not impart patentability to the claim because the prior art recognized the addition of non-ionic surfactant to reduce growth hormone aggregation, absent evidence to the contrary.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a formulation comprising growth hormone and non-ionic surfactant as disclosed by US '677 with the amount of the surfactant less than 0.05%, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

25. Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '677 in view of US '162.

The teachings of both references are discussed above.

US '677 does not teach the kit and the pen injector device as claimed in claims 31-34.

Thus, it would have been obvious to one having ordinary skill in the art the time of the invention to provide the formulation comprising growth hormone disclosed by US

'677, and administer the formulation by pen injector device comprising the growth hormone in a cartridge as disclosed by US '162, motivated by the teaching of US '162 that the device is suitable for lyophilized compounds that are moisture and oxygen sensitive such as growth hormone, with reasonable expectation of the having the formulation of US '677 comprising growth hormone delivered by pen injector device comprising cartridge containing the hormone and delivers it to the needy patient with great success.

26. Claims 10, 16, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '134.

The teachings of US '134 are discussed above, however, the reference does not teach the amount of the non-ionic surfactant as claimed in claims 10 and 16, or the specific surfactant as claimed in claim 22.

The specific non-ionic surfactant claimed in claim 22 does not impart patentability to the claim because the prior art recognized the addition of non-ionic surfactant to reduce growth hormone aggregation, absent evidence to the contrary.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a formulation comprising growth hormone and non-ionic surfactant as disclosed by US '134 with the amount of the surfactant to the desired concentration according to the specific need, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

27. Claims 28-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '134 in view of US '162.

The teachings of both references are discussed above.

US '134 does not teach the kit and the pen injector device as claimed in claims 28-34.

Thus, it would have been obvious to one having ordinary skill in the art the time of the invention to provide the formulation comprising growth hormone disclosed by US '134, and administer the formulation by pen injector device comprising the growth hormone in a cartridge as disclosed by US '162, motivated by the teaching of US '162 that the device is suitable for lyophilized compounds that are moisture and oxygen sensitive such as growth hormone, with reasonable expectation of the having the formulation of US '134 comprising growth hormone delivered by pen injector device comprising cartridge containing the hormone and delivers it to the needy patient with great success.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

IG

